



## Fast Track Proposed Regulation Agency Background Document

<b>Agency name</b>	Virginia Department of Agriculture and Consumer Services
<b>Virginia Administrative Code (VAC) citation</b>	2VAC5-501
<b>Regulation title</b>	Regulations Governing the Cooling, Storing, Sampling and Transporting of Milk
<b>Action title</b>	Amending 2VAC5-501 Based on Recommendations by the Attorney General's Government and Regulatory Reform Task Force
<b>Date this document prepared</b>	January 9, 2008

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

### Brief summary

*Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes.*

The proposed amendments to 2VAC5-501 would ensure that the same terms and words are used consistently throughout the regulation. Numerous citations to requirements have been updated to properly identify reference documents and citations to specific sections of the Code of Virginia to make the regulation more easily understood. The changes made are not substantive changes to the requirements of the regulation and do not create any new requirements or modify any existing requirements.

### Statement of final agency action

*Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.*

The Board of Agriculture and Consumer Services adopted amendments to 2VAC5-501, Regulations Governing the Cooling, Storing, Sampling and Transporting of Milk on December 6, 2007.

## Legal basis

*Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the scope of the legal authority and the extent to which the authority is mandatory or discretionary.*

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Sections 3.1-530.1, 3.1-530.2, 3.1-535, and 3.1-535.1 of the Code of Virginia (1950), provide the discretionary authority for the regulation. Section 3.1-530.1 of the Code of Virginia authorizes the Board of Agriculture and Consumer Services (Board) "...to establish definitions, standards of quality and identity, and to adopt and enforce regulations dealing with the issuance of permits, production, importation, processing, grading, labeling, and sanitary standards for milk, milk products, and those products manufactured or sold in semblance to or as substitutes therefor." Section 3.1-530.2 directs the Board to be guided by those regulations recommended from time to time by the United States Department of Health, Education and Welfare, and the United States Department of Agriculture when adopting regulations for the purpose of sanitation and to prevent deception. Section 3.1-535 authorizes the Board to make and enforce rules governing applications for certificates to manipulate the Babcock or other centrifugal machine for the purpose of determining the composition of milk or cream for purposes of inspection, to determine the composition or value of milk or cream, or to sample or weigh milk or cream as a basis for payment in buying or selling. Section 3.1-535.1 authorizes the Board "...to promulgate and enforce rules and regulations governing the equipment, standards, and procedures used in the receiving, weighing, measuring, sampling, and testing of milk or other fluid dairy products when the results are to be used for the purpose of inspection, check testing, or as a basis for payment in buying or selling."

## Purpose

*Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.*

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The goals of the regulation are to (1) protect the public's health and welfare with the least possible costs and intrusiveness to the citizens of the Commonwealth; (2) ensure the safety and quality of milk produced in Virginia by establishing temperatures at which milk must be kept on the farm and in the dairy plant, and by establishing equipment-design, construction, installation, and use requirements which protect milk from contamination during storage, transfer, and delivery; and (3) establish standards to be used in measuring, collecting, and evaluating milk samples for purposes of determining its components (such as fats, solids, and protein which are the basis for determining how much the farmer is to be paid for his milk) and its suitability (determined by the amount of bacteria it contains, among other things) for consumption by humans.

The regulation includes the milk of goats, sheep, water buffalo, and other mammals if the milk or dairy products are sold or offered for sale for human consumption. The primary purpose of the regulation is to ensure the safety and quality of all milk and milk products produced.

All milk and milk products have the same potential to carry pathogenic organisms. Numerous diseases of humans have been documented to be present in the milk of lactating mammals. Brucellosis and tuberculosis are two well-known and documented diseases which are capable of being spread from cows and goats to humans through their milk. Other common pathogens associated with milk and dairy products are: *Staphylococcus*, noted for its toxin production; *Streptococcus*, which causes strep-throat; *Campylobacter jejuni*, which infects the lining of the intestine and causes bloody diarrhea; *Escherichia coli*, which is responsible for causing bloody diarrhea and Hemolytic Uremic Syndrome; *Salmonella*, which also causes diarrhea; *Yersinia enterocolitica*, which causes severe abdominal pain; *Listeria monocytogenes*, which causes fever, vomiting, and can lead to still-births in pregnant women; and *Coxiella burnetii*, which causes Q fever. Some of these diseases can be fatal.

Milk is an excellent growth medium for most organisms including many pathogens. The fact that spoilage organisms and pathogens can grow in milk if they are present or introduced later by poor handling practices makes milk and milk products potentially hazardous if they are not properly processed, handled, packaged, and stored. The regulation ensures the safety and quality of milk by: (1) requiring all milk to be cooled and stored at temperatures that prevent or slow the growth of pathogens and spoilage organisms; (2) requiring milk to be cooled to storage temperatures quickly and maintained thereat to reduce the time pathogens and spoilage organisms have to grow while the temperature of the milk is being reduced to storage temperature; and (3) requiring minimum equipment-design, construction, installation, and use requirements that protect milk from contamination during storage, transfer, and delivery.

The regulation establishes standards to be used in measuring, collecting, and evaluating milk samples for purposes of determining its components (such as fats, solids, and protein which are the basis for determining how much the farmer is to be paid for his milk) and its suitability (determined by the amount of bacteria it contains, among other things) for consumption by humans. Milk samples used for inspection and pay purposes must be truly representative of the entire shipment of milk marketed to protect the buyer and the seller. The regulation establishes: (1) the procedures that must be followed to accurately measure the amount of milk being shipped; (2) the types of equipment that may be used to collect and store official milk samples; and (3) the minimum information that must be recorded on the seller's weigh ticket and the sample container.

The regulation also establishes chain of custody requirements for official milk samples by: (1) requiring persons to obtain a permit to weigh and sample milk prior to weighing or sampling any milk; (2) establishing sample collection, storage, and transportation procedures; (3) establishing equipment and records requirements; and (4) provisions for sample security. Establishing chain of custody for milk samples is essential to enforce the safety and quality requirements on permit holders. The inability of the Agency to establish chain of custody on any individual milk sample renders the results of laboratory tests on the sample unenforceable.

### Rationale for using fast track process

*Please explain the rationale for using the fast track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?*

*Please note: If an objection to the use of the fast-track process is received within the 60-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall (i) file notice of the objection with the Registrar of Regulations for publication in the Virginia Register, and (ii) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.*

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Each of the changes to the regulation were considered and recommended by the Attorney General's Government and Regulatory Reform Task Force, an initiative of Attorney General Robert F. McDonnell and have been reviewed and approved by the administration of Governor Timothy Kaine. All of the

changes are needed to make the regulation more understandable and “user-friendly”. None of the changes add any new requirements or modify any existing requirements. The regulation is essentially the same as before, except now it is more easily understood by the reader. During the public comment period there were no comments received that would conflict with any of the recommendations of the Government and Regulatory Reform Task Force and agency staff do not anticipate any controversy with any of the amendments.

**Substance**

*Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the “Detail of changes” section.)*

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There are no substantive changes to the regulation.

**Issues**

*Please identify the issues associated with the proposed regulatory action, including:*  
 1) *the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*  
 2) *the primary advantages and disadvantages to the agency or the Commonwealth; and*  
 3) *other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.*

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The primary advantage to the public and businesses of implementing the amended provisions is making the regulation easier to understand and user-friendly.

The primary advantage to the agency and Commonwealth is to foster voluntary compliance with the requirements because they are easier to understand and user-friendly.

There are no disadvantages to implementing the amended regulation.

**Requirements more restrictive than federal**

*Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.*

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There are no requirements that exceed applicable federal model regulations for states to adopt. Adoption of federal model regulations is voluntary, not mandatory. There are no applicable federal requirements adopted under federal regulations or law to the final regulation.

**Localities particularly affected**

*Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.*

There are no localities that will be particularly affected by the proposed regulation.

**Regulatory flexibility analysis**

*Please describe the agency’s analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.*

The agency has considered the following alternatives.

The first alternative considered was to establish less stringent requirements; however this alternative was rejected because less stringent cooling and storage requirements have not been shown to be effective in preventing increases in the number of bacteria in raw milk and milk products prior to pasteurization. If bacteria numbers increase significantly the ability of pasteurization to effectively kill all pathogens may be compromised and the safety of the resulting milk and dairy products would be questionable.

The second alternative considered was to establish performance standards for raw milk and dairy products that could be tested to determine their suitability to be effectively pasteurized; however, this alternative was rejected as impractical because laboratory testing would have to be performed on each lot of milk prior to pasteurization and test methods capable of obtaining test results within the time frame between milk pickup at the dairy farm and the start of pasteurization at the milk plant do not exist. Most laboratory methods for bacteria take two days to complete while most milk is processed within one day after receipt.

**Economic impact**

*Please identify the anticipated economic impact of the proposed regulation.*

<p><b>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going</b></p>	<p>There is no projected additional cost to the state to implement the regulation since there are no substantive changes.</p>
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<b>expenditures</b>	
<b>Projected cost of the regulation on localities</b>	There is no cost to localities since dairy farms, contract milk haulers and entities processing milk are not regulated by local government authority.
<b>Description of the individuals, businesses or other entities likely to be affected by the regulation</b>	The regulation affects any person or business who operates a dairy farm producing raw milk for grade "A" or manufacturing purposes, contracts to pickup and deliver raw milk from dairy farms to processing plants or who manufactures, processes, packages and sells any grade "A" (fluid milk, cottage cheese, cream, yogurt) or manufactured dairy products (butter, cheese, powdered milk, condensed milk).
<b>Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected.</b> Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.	The agency estimates there are seven hundred and fifty dairy farms, twenty-two contract milk haulers, and twenty-five dairy processors who qualify as small business affected by the regulation.
<b>All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.</b>	There are no additional projected costs of the regulation for affected individuals and businesses because all entities are in compliance with the current requirements.

**Alternatives**

*Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.*

The Agency has considered the following alternatives.

The first alternative considered was not to have this regulation, but the Agency rejects this alternative because the regulation ensures the efficacy of pasteurization. Also, this alternative would not comply with recommended standards of the United States Department of Health, Education and Welfare, or the United States Department of Agriculture. Failure to comply with these recommended standards would effectively bar the sale of milk outside of Virginia.

A second alternative considered was to institute a third-party certification program which would perform the necessary testing, inspection, and evaluation functions currently provided by Agency personnel. Third-party certification refers to a system in which a person, organization, or party, separate from either the dairy industry or the Agency, would perform necessary testing, inspection, and evaluation services.

Holders of permits, dairy farmers, milk-marketing cooperatives, and dairy plant processors would be charged a fee for services rendered through third-party certification. The Agency would have to continue to issue and renew all permits in order to take regulatory actions against permit holders. This alternative would transfer the majority of the cost of inspection, testing, and certification to industry while freeing Agency resources for use in other program areas. This alternative was rejected for the following reasons:

(i) the transfer of costs to industry from a program entirely funded through general funds would be an additional tax on the dairy industry; (ii) the dairy industry would likely pay much more in user fees than the Agency currently spends to operate the program; (iii) the Agency would have to create and operate a program to supervise and certify the third-party group, reducing the anticipated savings to the Agency; and (iv) legal concerns involving the chain of custody for milk samples and the ability to defend regulatory actions in administrative or court proceedings would be more complicated and cumbersome, further reducing any savings to the Agency.

The third alternative considered was to keep the regulation in its current form and continue to provide the required services through the Agency. This alternative was selected for the following reasons:

1. The Agency can operate the program more efficiently than other alternatives considered;
2. Confidence in the quality of milk samples used to determine the value of milk is enhanced by vesting the responsibility for the program with the Commonwealth; and
3. This alternative provides for a more uniform administration of the program statewide, since it is administered through just one office, which has control of all aspects of the program.

**Family impact**

*Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.*

The regulations do not have an impact on the institution of the family or family stability.

**Detail of changes**

*Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.*

*If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.*

For changes to existing regulations, use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
2 VAC 5-501-80		Farm Pickup and Transport tank construction and design	Properly cite references to 3-A Sanitary Standards for the design and construction of milk transport and

		requirements.	pickup vehicles to make them easily understood.
2 VAC 5-510-100		Interpretation and enforcement	Amended the section to use the same words and terms throughout and correct citations to specific sections to the Code of Virginia to make the regulation more understandable.